UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

In re CHEMBIO DIAGNOSTICS, INC. SECURITIES LITIGATION	Civil Action No. 2:20-cv-02706-ARR-JMW
	CLASS ACTION
This Document Relates To: ALL ACTIONS.	SECOND CONSOLIDATED AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS
	CONSOLIDATED CLASS ACTION

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Lead Plaintiffs Municipal Employees' Retirement System of Michigan ("MERS"), Special Situations Fund III QP, L.P. ("Fund III"), Special Situations Cayman Fund, L.P. ("Cayman Fund"), and Special Situations Private Equity Fund, L.P. ("PE Fund," and collectively with Fund III and Cayman Fund, the "Funds," and collectively with MERS, "Lead Plaintiffs"), by and through their undersigned attorneys, on behalf of themselves and all others similarly situated, allege the following based upon the investigation by Lead Counsel, except as to allegations specifically pertaining to Lead Plaintiffs, which are based on personal knowledge.

The investigation by Co-Lead Counsel included, among other things, a review of public filings with the United States Securities and Exchange Commission ("SEC") made by Chembio Diagnostics, Inc. ("Chembio" or the "Company"), press releases issued by the Company, public conference calls, media and news reports about the Company, and publicly available trading data relating to the price and volume of Chembio common stock. Lead Counsel believe that substantial evidentiary support for the allegations herein will be adduced after the opportunity for reasonable discovery.

INTRODUCTION

1. This is a federal securities class action brought on behalf of all persons who purchased Chembio common stock directly in or traceable to the Company's May 7, 2020 offering (the "Offering" or "May Offering") pursuant to Chembio's Form S-3 Registration Statement and its Prospectus and Prospectus Supplement, dated May 7, 2020 (together, the "Registration Statement"), which was conducted by Chembio and the Underwriter Defendants, Robert W. Baird & Co. Inc. ("Baird") and Dougherty & Company LLC ("Dougherty"). This class asserts claims only for

violations of Sections 11, 12(a)(2), and 15 of the Securities Act of 1933 (the "Securities Act"), 15 U.S.C. §§77k, 77l and 77o (the "Class").[1]

2. The claims on behalf of the Class concern untrue statements of material fact negligently made in the Registration Statement and omissions of material facts required to be stated in the Registration Statement or necessary to make the statements made therein not misleading. These misstatements and omissions were caused by Defendants' negligent and unreasonable preparation and issuance of the Registration Statement and failure to conduct a reasonable investigation into the accuracy of the factual statements set forth therein.

3. Chembio's business centers on developing diagnostic solutions and products for treatment, detection, and diagnosis of infectious diseases.

4. The Company claims to have developed and patented a new and innovative technology called the Dual Path Platform® ("DPP"), which allows for rapid diagnostic testing of a variety of infectious diseases and chemical substances.

5. On its website, the Company maintains that its products "meet the highest standards for accuracy and superior performance to help prevent the spread of infectious diseases" and that its "innovative solutions, like the Chembio Dual Path Platform (DPP®), make [point-of-care] testing faster, more accurate, and more cost effective."

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[1] Consistent with the Second Circuit's opinion in *Brown v. Daikin Am. Inc.*, 756 F.3d 219, 223 n. 1 (2d Cir. 2014), Lead Plaintiffs are only including claims arising under the Securities Act of 1933 in this complaint, as authorized by the Court, but are expressly reserving their rights to appeal any previously dismissed claims or defendants. *See id*. at 223 n.1 ("After the District Court dismissed with prejudice Brown's claims against DIL, Brown filed an Amended Complaint that included claims against only Daikin America. For purposes of evaluating the claims against DIL, we consider the allegations as pled in the initial Complaint."); *see also In re Crysen/Montenay Energy Co.*, 226 F.3d 160, 162 (2d Cir.2000) ("We see no reason to require repleading of a claim or defense that explicitly has been denied.").

6. On March 12, 2020, in response to the COVID-19 pandemic, Chembio announced its intention to create a COVID-19 antibody test using its preexisting DPP technology, and that it had entered into a worldwide strategic partnership with LumiraDx Limited ("LumiraDx"), a company focused on developing, manufacturing, and commercializing industry-leading point-of-care diagnostic platforms, with the aim of developing a diagnostic test for the detection of the COVID-19 virus and IgM and IgG antibodies on both of their DPP® platforms, later called the DPP COVID-19 IgM/IgG System (the "DPP COVID-19 Test," or the "Test").

7. This was part of the Company's "pivot" away from traditional revenue streams, like HIV and Zika point-of-care testing, to focus nearly exclusively on developing and marketing a suite of COVID-19 tests.

8. On April 14, 2020, the FDA granted an "Emergency Use Authorization" ("EUA") for the DPP COVID-19 Test, making it one of the first such tests to gain an EUA in an extremely competitive market. The EUA meant that Chembio might be able to bring the Test to the market and thereby capitalize on the growing need for COVID testing.

9. The data that Chembio provided the FDA – and upon which the FDA awarded the EUA – indicated clinical performance estimates of 77.4% positive percent agreement (PPA)/sensitivity for IgM, 87.1% PPA for IgG, 93.5% PPA for combined IgM/IgG, and 94.4% negative percent agreement (NPA)/specificity for combined IgM/IgG.

10. Immunoglobulin M ("IgM"), which is found mainly in the blood and lymph fluid, is the first antibody to be made by the body to fight a new infection and is commonly detectable after four to seven days. IgM antibodies are short-lived and may indicate that the virus is still present.

11. Immunoglobulin G ("IgG"), the most abundant type of antibody, is found in all body fluids and protects against bacterial and viral infections, is commonly produced seven to fourteen

days after infection, and is detectable for months and even years, depending upon the antigen and the individual. IgG antibodies are more durable than IgM antibodies and might provide lasting COVID-19 immunity.

12. Chembio and the Underwriter Defendants conducted the May Offering on May 11, 2020.

13. In the May Offering, Defendants sold approximately 2.6 million shares of Chembio stock at $11.75 per share directly to the public, including the Funds, for gross proceeds of approximately $30.8 million.

14. The Registration Statement for the May Offering stated that Chembio's Test was "100%" "accura[te]" "for total antibodies" and made numerous additional unequivocal representations about the commercial viability of the Test and the critical FDA EUA authorization that allowed the Company to sell the Test in the United States. The Registration Statement also warned of the risk to the Company should the FDA revoke the EUA, without ever disclosing that the EUA was already at an increased risk of being revoked.

15. On April 29, 2020, twelve days before the May Offering, the FDA notified the Chembio Defendants that new information from three evaluations performed since the initial EUA grant on April 14, 2020 demonstrated that Chembio's test performance may be "both inconsistent and lower than that described . . . ."

16. Specifically, data generated from an independent evaluation of Chembio's device by the National Institutes of Health ("NIH") and the National Cancer Institute ("NCI") demonstrated that relevant measures of the Test's accuracy fell below both the percentages in Chembio's initial submission and those deemed acceptable by the FDA.

17. Chembio had been notified at the time of its original submission to the FDA that the NCI would be conducting an independent evaluation, so the Company was in possession of information – well before the May Offering – that independent government agencies would be evaluating and seeking to confirm the Company's self-reporting test results.

18. Moreover, Chembio had submitted additional data to the FDA on April 29, 2020 and May 15, 2020 (a time frame encompassing the May Offering), which the FDA stated did not resolve the Agency's concerns regarding the poor clinical performance of Chembio's DPP COVID-19 Test. This included testing data from an independent evaluation conducted by the Richmond University Medical Center ("RUMC"), which showed that the Test actually performed worse than Chembio's initial data suggested (and indeed, as the Test was labeled), and far worse than the data upon which the EUA was based.

19. The Registration Statement was negligently prepared and unreasonably failed to disclose: (i) the notification from the FDA on April 29, 2020; (ii) that data generated by independent evaluations by NIH and NCI demonstrated measures of Test accuracy below those reported by Chembio and acceptable to the FDA; and (iii) that Chembio itself had submitted data from RUMC that showed the Test performed worse than Chembio reported.

20. Each of these facts was material to investors because each called into question the accuracy of the DPP Test and its domestic commercial viability, and indicated a substantially increased risk that the EUA might be revoked by the FDA.

21. Despite the obvious importance of this information to investors, as well as the public at large who were being put in danger by Chembio's marketing of an ineffective COVID diagnostic test, the Registration Statement negligently failed to disclose any of this material information.

22. Ultimately, the FDA had no choice but to notify the public and revoke the EUA. On June 16, 2020, after the market closed, the FDA issued a press release disclosing that it had revoked the Company's EUA for the DPP COVID-19 Test (the "Revocation"). In a public announcement, the FDA stated – consistent with its email to Chembio on April 29, 2020 – that its decision was "due to performance concerns with the accuracy of the test."

23. More specifically, the FDA informed Chembio that the Company's DPP COVID-19 Test "generate[d] a higher than expected rate of false results and higher than that reflected in the authorized labeling for the device." As a result, the FDA concluded that the "test's benefits no longer outweigh its risks." The FDA also sent a letter addressed to Chembio dated June 16, 2020 (the "FDA Letter"), notifying the Company of the Revocation and elaborating on how the FDA reached its decision.

24. The next day, on June 17, 2020, Chembio publicly acknowledged its receipt of the FDA Letter and informed the investing public of the FDA's revocation of its EUA. Immediately following this disclosure, at least five analysts downgraded Chembio stock.

25. After the disclosure of the FDA Letter and the revocation of the EUA, Chembio shares closed at $3.89 per share on June 17, 2020, significantly below the May Offering price of $11.75 per share.

JURISDICTION AND VENUE

26. The claims asserted herein arise under and pursuant to Sections 11, 12(a)(2), and 15 of the Securities Act, 15 U.S.C. §§77k, 771(a)(2).

27. This Court has jurisdiction over the subject matter of this action pursuant to Section 22 of the Securities Act and 28 U.S.C. §1331.

28. Venue is proper in this Judicial District pursuant to Section 22 of the Securities Act. Chembio is headquartered in this Judicial District, Defendants conduct business in this Judicial

District, and a significant portion of the acts and conduct complained of herein took place within this Judicial District.

29. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

A. Lead Plaintiffs

30. Lead Plaintiffs the Funds purchased Chembio common stock directly in the May Offering pursuant to the Registration Statement and have been damaged thereby.

31. The Funds collectively purchased 125,000 shares in the May Offering pursuant to the Registration Statement on the date of the Offering at the Offering price of $11.75 per share.

32. Lead Plaintiff MERS purchased Chembio common stock and was injured thereby, as set forth in its certification previously filed with the Court and incorporated herein by reference.

B. Defendants

33. Defendant Chembio is a Nevada corporation with its principal executive offices located at 555 Wireless Blvd., Hauppauge, NY 11788. Chembio's common stock trades in an efficient market on the NASDAQ Stock Market ("NASDAQ") under the ticker symbol "CEMI."

34. Together with its subsidiaries, Chembio develops, manufactures, and commercializes point-of-care ("POC") diagnostic tests that are used to detect or diagnose diseases. Historically, Chembio's primary business has been the design and sale of rapid diagnostic tests for, among other infectious diseases, HIV, HIV-Syphilis, Syphilis, Zika, Leishmaniasis, Chagas, and Ebola to customers such as hospitals, governmental and public health entities, non-governmental organizations, medical professionals, and retail establishments primarily located in the United States, Brazil, Europe, Malaysia and Mexico. Chembio Diagnostic Systems Inc., incorporated in Delaware,

is the operating subsidiary of Chembio Diagnostics, Inc. Together, the companies conduct Chembio's primary business of developing, manufacturing, marketing, and licensing POC diagnostic tests.

35. Defendant Gail S. Page ("Page") has served as Chembio's Executive Chair of the Board since April 23, 2020 and as a Director since 2017. Page served as Chembio's Interim CEO from January 2020 through March 15, 2020, and provided transitional services from March 16, 2020 through April 22, 2020. Page signed the Registration Statement.

36. Defendant Neil A. Goldman ("Goldman") has served as Chembio's Executive Vice President and Chief Financial Officer ("CFO") since December 2017. Goldman signed the Registration Statement.

37. Defendants Page and Goldman are referred to herein as the "Officer Defendants."

38. Defendant Katherine L. Davis ("Davis"), a director of Chembio, signed the Registration Statement.

39. Defendant Mary Lake Polan ("Polan"), a director of Chembio, signed the Registration Statement.

40. Defendant John Potthoff ("Potthoff"), a director of Chembio, signed the Registration Statement.

41. Defendants Davis, Polan and Potthoff are collectively referred to herein as the "Director Defendants" and are liable under the Securities Act by virtue of having signed the false and misleading Registration Statement.

42. Chembio, the Officer Defendants and the Director Defendants are collectively referred to herein as the "Chembio Defendants."

43. Defendant Robert W. Baird & Co. Inc. ("Baird") is a diversified financial services firm that, among other things, offers investment banking services to public issuers of securities. Its headquarters are located at 777 East Wisconsin Avenue, Milwaukee, WI, 53202.

44. Defendant Dougherty & Company LLC ("Dougherty") is a diversified financial services firm that, among other things, offers investment banking services to public issuers of securities. Its headquarters are located at 90 South Seventh Street, Suite 4300, Minneapolis, MN, 55402.

45. Defendants Baird and Dougherty are referred to herein as the "Underwriter Defendants." The Underwriter Defendants acted as underwriters of, and as sellers in, the May Offering. As shown in the chart below, from the Prospectus Supplement (defined below), the Underwriter Defendants received the following shares:

Underwriters	Number of Shares
Robert W. Baird & Co. Incorporated	1,987,698
Dougherty & Company LLC	350,770
Total	2,338,468

46. The Underwriter Defendants were also granted the option to buy up to an additional 350,770 shares of common stock, within 30 days from the date of the prospectus to exercise this option. If any shares were purchased pursuant to this option, the underwriters agreed to severally purchase shares in approximately the same proportion as set forth in the table above. If any additional shares of common stock were purchased, the underwriters agreed to offer the additional shares on the same terms as those on which the original shares were offered.

47. The Underwriter Defendants caused the Registration Statement to be filed with the SEC and to be declared effective in connection with the May Offering. They are liable under the Securities Act to Lead Plaintiffs and those similarly situated.

48. Chembio, the Officer Defendants, the Director Defendants, and the Underwriter Defendants are collectively referred to herein as "Defendants."

SUBSTANTIVE ALLEGATIONS UNDER THE SECURITIES ACT

49. As detailed below, the Registration Statement contained untrue statements of material fact, omitted to state other facts necessary to make the statements made not misleading, and was not reasonably prepared in accordance with SEC rules and regulations governing its preparation.

50. The Registration Statement negligently failed to disclose that the FDA had informed Chembio that independent tests conducted by NIH and NCI demonstrated measures of Test accuracy below those reported by Chembio or acceptable to the FDA. It also failed to disclose that Chembio itself had submitted data from RUMC that showed the Test performed worse than Chembio reported.

51. In preparing and issuing the Registration Statement, Defendants failed to undertake a reasonable investigation into the truth, accuracy, and completeness of the factual averments set forth in the Registration Statement. This is because, as discussed herein, Chembio was in possession of data that called into question the accuracy and effectiveness of the DPP COVID-19 Test and the continued viability of the FDA's EUA grant.

52. Each of these facts was material to investors because it would have informed them that Chembio was at much greater risk of having the Test's EUA authorization revoked by the FDA than represented.

53. Information concerning the accuracy of the DPP COVID-19 Test – particularly information from the independent government agencies reporting to the FDA – was material. Information indicating that the Test did not work as represented to the market and public health authorities, was likewise highly material.

54. Chembio's business model had shifted at the onset of the pandemic exclusively to COVID-19 testing and the entire thrust of the Company's business was now developing and

marketing the DPP COVID-19 Test. Thus, any increased risk that the Company could not market the DPP COVID-19 Test domestically could be devastating to the Company's business and future prospects and was therefore material.

A. Chembio's Point-of-Care Diagnostic Products

55. Chembio is a provider of point-of-care ("POC") diagnostic products for the detection and diagnosis of infectious diseases. POC testing refers to medical diagnostic testing that takes place at or near the time and place of patient care. It purportedly generates real-time, lab-quality diagnostic results within minutes through the use of portable blood analyzers, allowing medical personnel to make rapid triage and treatment decisions when diagnosing a patient or monitoring a treatment response.

56. Chembio's commercially available products employ either its proprietary DPP technology or traditional lateral flow technology. In the Registration Statement issued in connection with the May Offering, the Company claimed that while concurrently developing its own products, it had executed a strategy to leverage DPP intellectual property, as well as its scientific and operational expertise.

57. Chembio also disclosed that it was primarily focused on expanding its product portfolio based upon its proprietary DPP technology. Chembio's DPP technology is a form of lateral flow immunoassay (also referred to as lateral flow tests, referenced herein as "LFTs"), which is a diagnostic device used to confirm the presence or absence of a target analyte, such as pathogens or biomarkers in humans or animals, including antibodies or antigens.

58. The term "assay" is the technical term for an investigative procedure for measuring the presence, amount, or functional activity of a target entity.

B. The FDA Employs Emergency Use Authorization in Response to Increased Demand for COVID-19 Testing

59. In late 2019, a new virus called SARS-CoV-2, later designated as COVID-19, originated in China and spread rapidly, ultimately causing a massive global health crisis with a death toll that continues to rise, putting massive stress on the public and private health systems. On February 4, 2020, the Secretary of the Department of Health and Human Services determined, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act that there was a public health emergency with a significant potential to affect national security or the health and security of United States citizens living abroad.

60. The COVID-19 outbreak was declared a pandemic by the World Health Organization on March 11, 2020, and the United States declared a national emergency shortly thereafter on March 13, 2020.

61. In attempting to contain, control, and prevent the mass transmission of COVID-19, policy makers sought to work with private companies to develop COVID-19 tests, treatments, and vaccines.

62. Accurate methods of testing for COVID-19 were a vitally important tool for reducing the spread of the virus. Accurate diagnostic and serological tests that were readily accessible to the public could provide much-needed data on where the most serious outbreaks of the virus occur, and can offer insight into where medical and other resources should be allocated, and what public policy measures are appropriate or effective.

63. As a result, the demand for accurate tests skyrocketed. The sudden worldwide demand for accurate, high-quality testing was unlike anything the diagnostic testing industry had experienced before and placed unprecedented strain on companies attempting to tap into this new market.

64. The FDA took the extraordinary step of granting EUAs for COVID-19 diagnostic and antibody tests, allowing companies to market tests without receiving formal FDA approval.

65. The type of review that the FDA conducts for an EUA is considerably less rigorous than the normal process of reviewing a product for approval. Normally, to approve a drug, the FDA must determine that there is "substantial evidence," consisting of adequate and well-controlled investigations, that the product will have the effect it is intended to have.

66. An EUA, on the other hand, can be authorized if "it is reasonable to believe that . . . the product *may* be effective." The FDA assesses the potential effectiveness of possible EUA products on a case-by-case basis using a risk-benefit analysis, which takes the material threat which prompted the EUA declaration into account.

67. The FDA recommends that an EUA request include a well-organized summary of the available scientific evidence regarding the product's safety and effectiveness, risks and benefits, and any available, approved alternatives to the product. The FDA also states that companies are expected to continue to develop the product operating under an EUA.

68. In granting an EUA, the FDA makes clear that it will seek additional data and information on a case-by-case basis to ensure that its criteria are met.[2]

69. Consistent with that directive, the FDA's original letter of authorization for the EUA required Chembio to participate in the NCI study.

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[2] *Emergency Use Authorization of Medical Products and Related Authorities*, U.S. FOOD AND DRUG ADMINISTRATION (Jan. 2017), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities.

C. Background on Serology Testing

1. The Mechanics of Serology Testing

70. There are two types of relevant COVID-19 tests, diagnostic tests and serology tests, also known as antibody tests. There are two types of diagnostic tests: (1) molecular tests, such as RT-PCR tests, that detect the virus's genetic material; and (2) antigen tests that detect specific proteins from the virus. While diagnostic tests can determine if a person has an active coronavirus infection, serology tests, also known as antibody tests or immunoglobulin tests, can show if a person has been infected with COVID-19 in the past by detecting antibodies created by the immune system to fight the virus. Both are important tools in the efforts to address COVID-19.

71. Serology tests measure the level of certain antibodies, called immunoglobulins, which are proteins made by the immune system to fight antigens, such as bacteria, viruses, and toxins, in the blood. They are usually taken via finger stick or blood draw, and can provide results on the same day, or in 1-3 days. Antibodies are found in the liquid part of blood, called serum or plasma, and are specific to the particular infection they are produced to fight against.

72. The body produces different types of antibodies based on the time of infection. Relevant here, three types of antibodies are "IgA," "IgG," and "IgM." Immunoglobulin A ("IgA") is found in high concentrations in the mucous membranes, particularly those lining the respiratory passages and gastrointestinal tract, as well as in saliva and tears, and may increase during infection.

73. Immunoglobulin G ("IgG"), the most abundant type of antibody, is found in all body fluids and protects against bacterial and viral infections, is commonly produced seven to fourteen days after infection, and is detectable for months and even years, depending upon the antigen and the individual. They are more durable than IgM antibodies and may be the key to lasting COVID-19 immunity.

74. Immunoglobulin M ("IgM"), which is found mainly in the blood and lymph fluid, is the first antibody to be made by the body to fight a new infection and is commonly detectable after four to seven days. They are short-lived and may indicate that the virus is still present.

75. Antibodies in some individuals can be detected within the first week of illness onset. In COVID-19 infections, IgM and IgG antibodies can arise nearly simultaneously in serum within 2 to 3 weeks after illness onset, but it is unclear how long they remain detectable following an infection. Thus, the absence of detectable IgM or IgG antibodies does not necessarily rule out that a person could have previously been infected.

76. IgA, IgG, and IgM are often measured together, to increase test specificity and give doctors more information about immune system functioning. Total IgG and IgM assays cannot distinguish between early (IgM) and late (IgG) antibody responses, and as a result, do not provide a clear picture about whether an individual has potentially developed a longer-term immune response (IgG) or is currently infected (IgM).

77. Alternatively, an IgG-specific serology test reveals if a person had COVID-19 in the past and has developed antibodies that are highly specific to the virus. While it is still uncertain whether IgG antibodies offer lasting SARS-CoV-2 immunity, the IgG-specific test is still able to tell clinicians of a past infection, which can provide important information regarding individual and population immunity levels.

2. The Importance of Serology Testing for COVID-19

78. Numerous serologic assays for SARS-CoV-2 were granted EUAs in recognition of their importance in fighting the COVID-19 pandemic. Although serology tests do not detect the presence of the SARS-CoV-2 virus itself, they can help determine whether the individual being tested was previously infected, even if that person never showed symptoms, unlike direct detection methods, such as antigen detection tests, that can detect acutely infected persons.

79. As a result, serology tests can illuminate the population's level of immunity, a key tool in society's efforts to move past the pandemic. While serologic assays do not typically replace direct detection methods as the primary tool for diagnosing an active SARS-CoV-2 infection, they are sometimes performed along with viral testing when someone seeks care late in the course of their illness. They may also help confirm a diagnosis of Multisystem Inflammatory Syndrome in Children, a condition linked to COVID-19.

80. Serology tests have numerous important applications in monitoring and responding to the COVID-19 pandemic. Not everyone who has had COVID-19 had the opportunity to be tested before the virus was cleared from their bodies, and studies conducted on the transmission of COVID-19 to date have shown that up to 44% of those who test positive are asymptomatic. Thus, serologic assays for SARS-CoV-2 can play an important role in understanding the virus's epidemiology in the general population and identifying groups at higher risk for infection.

81. Demographic and geographic patterns of serologic test results can also help determine which communities may have experienced a higher infection rate and therefore may have a higher proportion with some degree of immunity, at least temporarily.

82. It is now presumed that there is a significant population in the United States that likely has been infected with SARS-CoV-2, has recovered, and currently possesses some degree of immunity. Extensive serology testing would help determine the true prevalence of COVID-19, which would aid public health decision-making, release individuals from the constraints of social distancing measures, and eventually restart the economy.

83. Serologic test results can also assist in determining who may donate a part of their blood called convalescent plasma, which may serve as a possible treatment for those who are seriously ill from COVID-19.

D. Measuring the Effectiveness of Serology Tests

84. The performance of serology tests is described by their "sensitivity," or their ability to identify those with antibodies to SARS-CoV-2 (true positive rate), and their "specificity," or their ability to identify those without antibodies to SARS-CoV-2 (true negative rate).

85. A highly sensitive test will flag almost everyone who has the condition being tested for and will not produce many false-negative results. For example, a test with 90% sensitivity will correctly return a positive result for 90% of people who are positive for the condition they are being tested for, but will return a negative result, *i.e.*, a false-negative, for 10% of the people who should have tested positive. A more specific test will detect only the presence of the specific antibodies of interest and produce few false positive results. However, because the presence of both IgM and IgG vary depending on when the infection occurred, the timing of testing is critical.

86. A test's sensitivity can be estimated by determining whether or not it is able to detect antibodies in blood samples from patients who have been confirmed to have COVID-19 with a nucleic acid amplification test, or NAAT. In some validation studies of these tests, the samples used, in addition to coming from patients confirmed to have COVID-19 by a NAAT, may also be confirmed to have antibodies present using other serology tests.

87. Specificity measures a test's ability to correctly generate a negative result for individuals who do not have the condition being tested for. A high-specificity test will correctly rule out almost everyone who does not have the condition and will not generate many false-positive results. For example, a test with 90% specificity will correctly return a negative result for 90% of people who don't have the condition, but will return a false positive for 10% of the people who do not have the condition and should have tested negative.

88. A test's specificity can be estimated by testing large numbers of samples collected and frozen before SARS-CoV-2 is known to have circulated to demonstrate that the test does not

produce positive results in response to the presence of other causes of a respiratory infection, such as other coronaviruses.

89. Tests are also described by their Positive Predictive Value ("PPV") and Negative Predictive Value ("NPV"). The term "predictive value" refers to the probability of having the condition, given the results of the test. Positive predictive value is the probability that a patient with a positive test result actually has the condition. Negative predictive value is the probability that a person with a negative test result is truly free of the condition.

90. These measures are calculated using a test's sensitivity, specificity, and using an assumption about the percentage of individuals in the population who have antibodies to SARS-CoV-2 (which is called "prevalence" in these calculations). The more sensitive a test, the less likely an individual with a negative test will have the condition and thus the greater the negative predictive value. The more specific the test, the less likely an individual with a positive test will be free from the condition and the greater the positive predictive value.

91. Every test returns some false positive and false negative results. The PPV and NPV help test interpreters understand, given how prevalent individuals with antibodies are in a population, how likely it is that a person who receives a positive result from a test truly does have antibodies to SARS-CoV-2, and how likely it is that a person who receives a negative result from a test truly does not have antibodies to SARS-CoV-2.

92. When the prevalence of preclinical disease is low, the positive predictive value will also be low, even using a test with high sensitivity and specificity. For rarer diseases, a large proportion of those with positive screening tests will inevitably be found not to have the disease upon further diagnostic testing.

93. To increase the positive predictive value of a screening test, a program could target the screening test to those at high risk of developing the disease, based on considerations such as demographic factors, medical history or occupation. For example, mammograms are recommended for women over the age of forty, because that is a population with a higher prevalence of breast cancer.

94. In response to COVID-19, experts maintain that antibody test manufacturers must have a heightened focus on specificity to reduce the number of instances where individuals falsely believe they have a certain level of immunity and are safe to relax social distancing precautions.

E. The DPP COVID-19 Test

95. The Chembio DPP COVID-19 Test was a single-use rapid immunochromatographic test for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in fingerstick whole blood, venous whole blood, serum, or plasma (lithium heparin or EDTA) samples.

96. On April 8, 2020, prior to the EUA grant, Chembio announced that Stony Brook Medicine selected the DPP COVID-19 Test to help identify persons who have recovered from COVID-19 for use in an FDA-approved investigation to determine if convalescent blood plasma from people who have recovered from COVID-19 can help treat hospitalized patients with active COVID-19 infection. The DPP COVID-19 System was used to confirm that patients enrolled in Stony Brook's study had adequate levels of IgG antibodies to make them eligible to donate convalescent plasma.

97. The DPP COVID-19 Test was granted an EUA by the FDA on April 14, 2020 based on data Chembio submitted to the FDA which claimed clinical performance estimates of 77.4% positive percent agreement (PPA)/sensitivity for IgM, 87.1% PPA for IgG, 93.5% PPA for combined IgM/IgG, and 94.4% negative percent agreement (NPA)/specificity for combined IgM/IgG.

98. The DPP COVID-19 IgM/IgG System included the DPP COVID-19 IgM/IgG Test Devices and the DPP Micro Reader or DPP Micro Reader 2 for use with the DPP COVID-19 IgM/IgG System. The test was made specifically to be read with the DPP Micro Reader or the DPP Micro Reader II.

F. The FDA Questions the Accuracy of Chembio's DPP COVID-19 Test, Provides Contrary NIH and NCI Data that Indicates the Test is Ineffective, and Provides Information to Chembio Indicating that the EUA is at Risk

99. As noted above, Chembio was granted an EUA for its DPP COVID-19 Test on April 14, 2020 based on clinical performance data it submitted to the FDA of 77.4% positive percent agreement (PPA)/sensitivity for IgM, 87.1% PPA for IgG, 93.5% PPA for combined IgM/IgG, and 94.4% negative percent agreement (NPA)/specificity for combined IgM/IgG. Based on Chembio's data, the EUA allowed Chembio to immediately market and sell the DPP Test in the United States as a diagnostic test to evaluate the presence of COVID-19 antibodies.

100. As analysts at Craig-Hallum (which followed Chembio stock) explained to investors, the benefit of Chembio's test was its ability to distinguish those who were contagious from those who were not:

> [Chembio's] DPP COVID-19 [Test] is a rapid serological point-of-care test for the detection of IgM and IgG antibodies. We would liken IgM antibodies to first responders, as [the] body generates these first at the sign of infection; in time, the IgM antibodies fade and IgG antibodies take over. Thus the DPP [T]est can help distinguish acute/active infection via IgM (and thus whether that person can transmit the virus) and prior infection via IgG (not likely to transmit the virus). . . . [R]esults are obtained within 15 minutes using a simple finger stick of blood. . . . [T]he Chembio DPP [COVID-19 T]est is able to provide a quantitative result, which could assist clinicians in determining patients who have been exposed to Coronavirus, irrespective of whether they are asymptomatic.

101. Test accuracy is the principal concern for serology tests like Chembio's DPP COVID-19 Test. FDA EUA is a seal of approval for such tests, and analysts covering Chembio's stock at that time concluded that FDA EUA is the "line in sand" separating reliable and accurate serology

tests from the numerous dysfunctional or low-performing tests that were expected to enter the market at the outset of the pandemic.

102. As a general matter, patients and their healthcare providers are more likely to seek out diagnostic tests that have met with FDA approval than alternative tests that have not been found to be as reliable.

103. At the time it received an EUA from the FDA, Chembio was the only publicly traded company with such authorization.

104. In response to Chembio's announcement that it had received an EUA from the FDA, Chembio's stock price increased rapidly, and analysts covering Chembio's stock increased their price targets for the Company, noting that, according to Canaccord Genuity on April 15, 2020, for example, the EUA "further 'legitimizes' CEMI's COVID-19 revenue opportunity and the [121% year to date] return for its stock."

105. However, the FDA privately informed Chembio by April 29, 2020 that independent evaluation of Chembio's DPP COVID-19 Test by third parties, including the NIH and NCI, provided information to the FDA that indicated that Chembio's prior data was inaccurate and that the DPP COVID-19 Test was ineffective.

106. In an April 29, 2020 phone call with Chembio, the FDA informed Chembio that results from the NCI's testing of a panel of 110 blood specimens using the DPP COVID-19 System failed to replicate the accuracy of the data Chembio submitted to the FDA to obtain the EUA.

107. This information was material to Chembio's investors.

108. For example, by April 29, 2020, Chembio was exclusively focused on selling the Test and needed to maintain the EUA to do so.

109. During the April 29, 2020 call, the FDA stated that it "had concerns regarding the results of the NCI evaluation . . . ." and also told Chembio that data generated from an independent evaluation of Chembio's device by the National Institutes of Health and the NCI demonstrated an observed PPA of 57.1% for IgM, 78.6% for IgG, and 82.1% for combined IgM/IgG, which indicates a high false negative rate. The overall NPA was 81.2%, which indicates a high false positive rate.

110. The original testing report of the NCI evaluation was provided to Chembio on April 30, 2020. This data suggested "significant performance concerns" with the Test, because it demonstrated a high false positive rate, which lowered specificity to 81.2%, far lower than Chembio's representation of 94.4%. This demonstrated an increase in false positives of more than 12%. The NCI asserted that such false positives were "unacceptable":

> [NCI] demonstrated an unacceptable high false positive rate for overall (combined IgM/IgG) specificity of 81.2%. The difference between the specificity observed in this independent evaluation and the labeled specificity of [the Test] incurs an unacceptable risk of clinically significant harm to patients due to the frequency with which false results are expected to occur. Specifically, the specificity described in your labeling is 94.4% for specimens collected prior to March 2019, *i.e.*, prior to the current pandemic. When considering the low prevalence of individuals with antibodies to SARS-CoV-2 expected in the United States, the difference between the labeled performance of [the Test] and the specificity observed in the NCI evaluation (81.2%) is concerning. For example, when considering a prevalence of individuals with infection of 5%, the difference would result in 1,254 more people per 10,000 people tested being identified as having antibodies when they are truly negative (*i.e.*, false positive).

111. The FDA stated that these results were "both inconsistent and lower than that described in [Chembio's] original submission" and "demonstrated unacceptable high false negative rates for IgM, IgG and overall (combined IgM/IgG) sensitivity."

112. According to the FDA, the differences between the sensitivities demonstrated by the NCI evaluation and the data on which the EUA was based, and the specific labeling of the DPP COVID-19 Test, led to an "unacceptable risk of clinically significant harm to patients due to the frequency with which false results are expected to occur."

113. This information notified Chembio that there was in fact an increased risk that the EUA would not be maintained by the FDA. A reasonable issuer of securities in Chembio's position would have disclosed such information to its investors.

114. Indeed, the subject line of the email sent to Chembio relaying the results of the NCI study, and recounting the FDA's April 29 phone call, was "EUA200179, risk concerns, response required."

115. In addition, Chembio submitted additional information regarding the Test on April 29, 2020, May 4, 2020, and May 7, 2020, which also gave the FDA concerns about the Test's poor efficacy.

116. In particular, on April 29, 2020, Chembio provided the FDA with independent results from Richmond University Medical Center that showed a virtually identical overall specificity rate of 81.4%, corroborating the "unacceptable" false positive rate observed by NCI:

> [Chembio] provided results from an independent study conducted by Richmond University Medical Center. The combined data for RUMC hospital patients and employees with positive PCR results showed PPAs of 61.0% for IgG, 81.4% for IgM, and 81.4% for overall. These results show a lower sensitivity for IgG, IgM and overall compared to the labeled performance of [the Test], which incur an unacceptable risk of clinically significant harm to patients due to the frequency with which false results are expected to occur.

117. Elsewhere, on May 4 and May 7, Chembio provided to the FDA results from certain additional testing it, along with Stony Brook University Hospital, performed. While some of this data was supportive of Chembio's original submission, the FDA did not have information sufficient to interpret that data.

118. Moreover, Chembio's submission also demonstrated that the Test's performance was different in a "clinically significant" way from its labeled performance.

119. The performance demonstrated in the independent evaluation was below the clinical performance that the FDA generally expects for serology tests to meet the effectiveness and

risk/benefit standards for issuance of an EUA. It would have been reasonable and prudent to disclose this information to investors, because it implicated and called into question Chembio's ability to maintain the EUA and market the Test.

120. In the FDA Letter, the FDA stated that clinical agreement data for SARS-CoV-2 antibody tests with 30 positive samples and 75 negative samples generally should demonstrate a minimum combined PPA/sensitivity, of 90%; a minimum NPA/specificity, of 95%; and for tests that report specifically IgM and IgG, a minimum PPA/sensitivity for IgG of 90% and a minimum PPA/sensitivity for IgM of 70%. Clinical agreement data for SARS-CoV-2 antibody tests with greater than 30 positives and 75 negative samples generally should demonstrate a minimum overall (*i.e.*, IgM/IgG combined) and IgG PPA of 87% with a lower bound of the 95% confidence interval greater than 74.4%, a minimum IgM PPA of 67% with a lower bound of the 95% confidence interval greater than 52.1%, and a minimum NPA of 93% with a lower bound of the 95% confidence interval greater than 87.8%.

121. By contrast, the NCI study demonstrated an unacceptable high false positive rate for the DPP Test of ***81.2%*** for overall (combined IgM/IgG) specificity.

122. As a result, as of April 29, 2020, the data Chembio included in its EUA submission was demonstrably insufficient to maintain EUA approval from the FDA and fell far below the FDA's standards for granting and maintaining EUAs.

123. Indeed, by the time of the May Offering, Chembio had been informed that the FDA believed there were "significant performance concerns" with the DPP COVID-19 Test, which the FDA believed "may put patients at unreasonable risk of harm due to inaccurate results."

124. At the time of the May Offering, the DPP COVID-19 Test was producing unacceptable levels of false positives in tests conducted by independent third parties, materially

below the results Chembio had submitted to the FDA; the FDA had notified Chembio of these concerns; and Chembio had already submitted additional data to the FDA in an effort to resolve those concerns that corroborated the deficient results, and undermined the results upon which the EUA was granted initially.

125. These facts, and the enhanced risks they presented, were negligently omitted from the Registration Statement.

G. The Registration Statement Negligently Failed to Disclose the Actual Performance of the DPP COVID-19 Test, Contrary Information Demonstrating the Test's Poor Performance, and the Increased Risk the EUA Would Be Revoked

126. On October 3, 2018, Chembio filed a shelf Registration Statement with the SEC.

127. On May 7, 2020, the Prospectus for the May Offering, which forms part of the Registration Statement, became effective. Thereafter, Defendants, including the Underwriter Defendants, offered and sold approximately 2,619,593 shares of Chembio common stock, which included 281,125 shares issued pursuant to the partial exercise by the underwriters of their option to purchase additional shares, at a public offering price of $11.75 per share for gross proceeds to Chembio of approximately $30.8 million.

128. Specifically, the Registration Statement stated that Chembio's DPP COVID-19 Test was 100% accurate for total antibodies after 11 days:

> In February 2020, we began to shift substantially all of our resources to leverage our DPP lateral flow technology to address the acute and escalating need for an accurate diagnostic test for COVID-19. By March 2020 we had developed, and begun to manufacture for commercialization, the DPP COVID-19 System, which consists of our new serological test for COVID-19 and our Micro Reader analyzer. The DPP COVID-19 System can provide discrete, numerical readings for IgM and IgG antibody levels in approximately 15 minutes from a fingerstick drop of blood. ***The accuracy of the DPP COVID-19 System after 11 days post the onset of symptoms is 100% for total antibodies.***

129. The statements referenced above in ¶128 were untrue statements of material fact and omitted to state other facts necessary to make the statements not misleading because, at the time of the Registration Statement, the accuracy of the DPP COVID-19 System after 11 days post the onset of symptoms was not 100% for total antibodies. Chembio had received data that called into question the accuracy of this information, including through the independent NCI and NIH study, as well as the RUMC and Stony Brook University evaluation (discussed *supra* at ¶¶16-19, 96, 105-122). Among other things, this data indicated that false results for individuals in those evaluations occurred more than eleven days after the onset of symptoms. A reasonable and prudent issuer in Chembio's position would have disclosed this contrary data to investors when selling stock to them in a registered offering.

130. In addition, this statement concerned the accuracy of the DPP COVID-19 System based exclusively on Chembio's original data set in support of the EUA. Consequently, the Registration Statement negligently omitted to disclose contrary information in Chembio's possession, including the NCI and RUMC data sets.

131. This statement was also an untrue statement of material fact because it was unequivocal and referenced "100%" accuracy, even though the Test's accuracy had actually been called into question by third party diagnostic testing – as well as the RUMC testing provided by Chembio itself – that indicated flawed performance. It was not reasonable to omit to disclose such information.

132. The Registration Statement also discussed the Company's focus on the "manufacture and commercialization of the DPP COVID-19 System," stating:

> Prior to shifting our focus to COVID-19 testing in February 2020, we had established our company as a leading provider of diagnostic tests for infectious diseases with a broad portfolio of infectious disease products. ***We refer to our infectious disease products, other than the DPP COVID-19 System, as our legacy products. We***

> ***expect to generate an immaterial amount of revenue from our legacy products for the foreseeable future, while we continue to focus on the manufacture and commercialization of the DPP COVID-19 System.*** Thereafter, however, we intend to recommence the development, marketing, manufacture and sale of the legacy product portfolio consistent with market demand.

133. The statements referenced above in ¶132 were untrue statements of material fact and omitted to state other facts necessary to make the statements not misleading because they negligently failed to disclose that, at the time of the Registration Statement, the continued approval of the DPP COVID-19 System's EUA was in question.

134. The Registration Statement also negligently failed to disclose that, at the time of the May Offering, Chembio had been informed that the FDA had expressed concerns about the reliability of the data Chembio had submitted with its EUA application and that there was an increased risk that its EUA for the DPP COVID-19 System would be revoked.

135. While the Registration Statement addressed other risks associated with FDA review and the EUA grant, it negligently and unreasonably did not disclose that the EUA grant was at a greater risk of being revoked, and the DPP Test rendered unmarketable, as a result of independent analyses that demonstrated the DPP Test's lack of efficacy. For example, the Registration Statement warned that:

> [Chembio's] DPP COVID-19 System is subject to regulations of the U.S. Food and Drug Administration, or FDA, International Organization for Standards and other regulatory requirements. The regulations regarding the manufacture and sale of our DPP COVID-19 System ***may be unclear and are subject to change. Newly promulgated regulations could require changes to our DPP COVID-19 System, necessitate additional procedures, or make it impractical or impossible for us to market our DPP COVID-19 System for certain uses, in certain markets, or at all.*** The FDA and other regulatory authorities also have the ability to ***impose new or additional requirements*** relating to our DPP COVID-19 System. The implementation of such ***changes or new or additional requirements*** may result in substantial additional costs and could delay or make it more difficult or complicated to sell our products.
>
> The FDA issued an Emergency Use Authorization, or EUA, for emergency use of the DPP COVID-19 System. The FDA has established certain conditions that must be

> met to maintain authorization under an EUA, and the ***FDA also has the power to revoke the EUA under which our DPP COVID-19 System is sold if it determines that the underlying health emergency no longer exists or warrants such authorization.*** Such revocation would preclude the sale of our COVID-19 product unless and until a further regulatory approval or authorization is obtained. We cannot predict the effect, if any, that these changes might have on our business, financial condition or results of operations.
>
> In addition, the EUA issued by the FDA for emergency use of the DPP COVID-19 System is limited to authorized laboratories certified under CLIA to perform moderate and high complexity tests. We are currently working with the FDA to approve our application for waived status under CLIA, which would permit any laboratory with a Certificate of Waiver, including physician offices and urgent care clinics, to perform the tests. ***The time required to obtain marketing authorizations and other approvals from regulatory authorities is unpredictable.*** The standards that the FDA and its foreign counterparts use when evaluating clinical trial data can change, and does often change, during development, which makes it difficult to predict with any certainty how they will be applied. ***We may also encounter unexpected delays or increased costs due to new government regulations, including future legislation or administrative action, or changes in FDA policy during the period of FDA regulatory review.***

136. The statements referenced above in ¶135 were untrue statements of material fact and omitted to state other facts necessary to make the statements not misleading because they negligently failed to disclose a known risk that had already materialized – that an independent evaluation of the DPP COVID-19 Test obtained by the FDA (generated by the NIH and NCI) had revealed "unacceptable" results below those represented by Chembio, that the Test was in fact far less effective than the threshold necessary to maintain EUA, and thus the Test was at an increased risk of losing its EUA.

137. Indeed, Chembio had previously been told of, but did not disclose, facts that increased the risk of EUA revocation when the FDA expressed its concern that the Test "may put patients at unreasonable risk of harm due to inaccurate results." It would have been reasonable and prudent to disclose this information in connection with a registered offering of stock to Chembio's investors.

138. Chembio's warning referencing the possibility of FDA revocation (*supra* at ¶135) was also an untrue statement of material fact and omitted to state other facts necessary to make the statement not misleading because it only identified as a risk the possibility that the FDA may determine that the "underlying health emergency" – *i.e.*, the COVID-19 pandemic – "no longer exists or warrants such authorization."

139. This warning negligently omitted to disclose what was in fact the key risk to the EUA – the poor performance of the DPP Test and its "unacceptable" level of false positive results – as a potential risk to the Company maintaining the EUA.

140. The Registration Statement also negligently described the Company's ability to leverage its DPP platform to create an accurate COVID-19 serological test, and to similarly expand into other types of diseases. Chembio implied that it had quickly developed an effective test, when in fact its DPP Test was producing an unacceptably high percentage of false positives:

> When the novel coronavirus emerged, we were confident that we could leverage our DPP platform and our scientific and operational expertise to create an antibody test to detect and diagnose the presence, or former presence, of antibodies generated in response to the virus. ***The speed with which we were able to develop a test for COVID-19 illustrates the DPP platform's applicability to new and emerging infectious diseases.***

141. The statements referenced above in ¶140 were untrue statements of material fact and omitted to state other facts necessary to make the statements made not misleading. While the Company had rapidly developed a test for COVID-19, it was not reasonable or prudent to tell investors that the Test applied to the COVID pandemic while also not disclosing that contrary data indicated the Test was ineffectual at reliably diagnosing infections.

142. The Registration Statement also negligently failed to disclose that Chembio had been informed by the FDA that the Test actually performed worse than the accuracy indicated by the information underlying, and securing, the EUA, and that independent testing data Chembio itself

received and sent to the FDA was consistent with the information the FDA had obtained and provided to Chembio, with both sets of data corroborating the inaccuracy of the Test and calling into question the data the Company had previously submitted to support the use of the DPP Test in connection with the COVID-19 pandemic.

H. The FDA Announces it is Revoking the EUA and Chembio's Stock Price Declines

143. On June 16, 2020, after the market closed, the FDA issued a press release disclosing the Revocation of Chembio's EUA.

144. The Agency stated that its decision was "due to performance concerns with the accuracy of the [T]est," and that the FDA had notified the Company about those performance concerns prior to the May Offering.

145. Following this announcement, Chembio shares closed at $3.89 per share on June 17, 2020.

I. The Registration Statement Failed to Disclose Information Required by Items 303 and 105 of Regulation S-K

146. In addition to the untrue statements of material fact in the Registration Statement identified above, Defendants also violated their affirmative obligations to provide certain material information in the Registration Statement as required by applicable SEC rules and regulations.

147. Item 303 of SEC Regulation S-K, 17 C.F.R. §229.303 ("Item 303"), requires the Registration Statement to "[d]escribe any ***known*** trends or ***uncertainties*** that have had or that the registrant reasonably expects will have a materially favorable and unfavorable impact on the sales or revenues or income from continuing operations."

148. In May 1989, the SEC issued an interpretive release on Item 303 ("1989 Interpretive Release"), stating, in pertinent part, as follows:

> Required disclosure is based on ***currently known*** trends, events, and ***uncertainties*** that are reasonably expected to have material effects, such as: A reduction in the registrant's product prices; erosion in the registrant's market share; changes in insurance coverage; or the likely non-renewal of a material contract.
>
> * * *
>
> ***A disclosure duty exists where*** a trend, demand, commitment, event or ***uncertainty is both presently known to management and reasonably likely to have material effects on the registrant's financial condition or results of operation***.

149. Further, the 1989 Interpretive Release sets forth the following test to determine if disclosure under Item 303(a) is required:

> Where a trend, demand, commitment, event or uncertainty is known, management must make two assessments:
>
> (1) Is the known trend, demand, commitment, event or uncertainty likely to come to fruition? If management determines that it is not reasonably likely to occur, no disclosure is required.
>
> (2) If management cannot make that determination, it must evaluate objectively the consequences of the known trend, demand, commitment, event or uncertainty, on the assumption that it will come to fruition. Disclosure is then required unless management determines that a material effect on the registrant's financial condition or results of operations is not reasonably likely to occur.

150. The FDA's notification to Chembio about the performance of its Test based on results it obtained from independent third parties, including the NIH and NCI, created a "known uncertainty" that was required to be disclosed.

151. By the time of the May Offering, the FDA had already communicated to Chembio that the data Chembio provided to support its EUA application was overstated and inconsistent with that of independent evaluations of the DPP COVID-19 System that the FDA had obtained, including from the NIH and NCI. The independent data concluded that the Test had an unacceptable level of false positives. That same day, Chembio also provided independent testing data that was consistent with the poor performance of its Test.

152. Thus, whether the FDA would continue to allow the EUA for the DPP COVID-19 System based on the data and application submitted was a known uncertainty that was likely to have a material unfavorable impact on the Company's revenues and income from continuing operations. It was therefore required to be disclosed in the Registration Statement but was not.

153. In addition, Item 105 of SEC Regulation S-K, 17 C.F.R. §229.105 ("Item 105"), required that the "Risk Factors" section of the Registration Statement disclose the most significant factors that made the May Offering risky or speculative, and that each risk factor adequately describe the risk.

154. The Registration Statement did not disclose that Chembio had provided the data to the FDA about the accuracy of its Test and that the FDA had said independent testing agencies did not corroborate the data.

155. The Registration Statement also failed to disclose that there was a risk that the data Chembio provided to the FDA would be inconsistent with the results of independent agencies and that an unacceptable level of performance could result in a revocation of the EUA. There was in fact an increased (but undisclosed) risk that Chembio's EUA for the DPP COVID-19 System could be revoked because the FDA had told Chembio that data underlying Chembio's EUA application was overstated and inconsistent with that of independent evaluations it had obtained of the DPP COVID-19 System. Because this risk was not disclosed, Defendants violated Item 105.

J. The Role of the Underwriter Defendants in Connection with the May Offering

156. The May Offering was a firm commitment offering conducted by and through the Underwriter Defendants, a syndicate consisting of Baird acting as sole book-running manager and Dougherty as co-manager.

157. The Underwriter Defendants are liable under the Securities Act as detailed below.

158. The Underwriter Defendants are investment banking houses that, among other things, specialize in underwriting public offerings of securities. They served as the underwriters of the May Offering and shared more than one million dollars in fees collectively for doing so.

159. The Underwriter Defendants also assisted Chembio in planning the May Offering, and had access to confidential corporate information concerning Chembio's operations and financial prospects, including information regarding the efficacy of the DPP COVID-19 Test and the FDA's response to the Company in connection therewith.

160. In addition to availing themselves of access to internal corporate documents, on information and belief, agents of the Underwriter Defendants met with Chembio's lawyers, management, and top executives in the month leading up to the May Offering.

161. During these meetings, agreements were reached as to: (i) the strategy to best accomplish the May Offering; (ii) the terms of the May Offering, including the price at which Chembio common stock would be sold; (iii) the language to be used in the Registration Statement; (iv) what disclosures would be made in the Registration Statement; and (v) what responses would be made to the SEC in connection with its review of the Registration Statement.

162. As a result of those frequent contacts and communications between the Underwriter Defendants and the Chembio Defendants (as well as the Underwriter Defendants' direct involvement in material issues requiring disclosure, including Chembio's business performance and reported financial information), the Underwriter Defendants knew of, or in the exercise of reasonable care should have known of, the existing yet undisclosed conditions and material risks detailed herein, which were either misrepresented in or omitted from the Registration Statement.

163. At a minimum, the Underwriter Defendants were negligent in not knowing, and failing to disclose in connection with the May Offering, the adverse information about the DPP

COVID-19 Test conveyed by the FDA to the Company before the Offering, as well as adverse information about the effectiveness of the Test that was contrary to the disclosures in the Registration Statement, the omission of which rendered the Registration Statement false and misleading at the time it was made effective.

164. The Underwriter Defendants did not conduct adequate due diligence. Had the Underwriter Defendants done so, they would have known that the Registration Statement was materially false or misleading or omitted to state material information or information required to be disclosed.

165. The Underwriter Defendants helped cause the Registration Statement to be filed with the SEC and declared effective in connection with the offer and sale of the shares of Chembio common stock registered thereby, including those shares purchased by the Funds and other members of the Class.

CLASS ACTION ALLEGATIONS

166. Lead Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and 23(b)(3) on behalf of all persons who purchased Chembio common stock directly in or traceable to the May Offering pursuant to the Registration Statement and Prospectus. This class asserts claims for violations of Sections 11, 12(a)(2), and 15 of the Securities Act, 15 U.S.C. §§77k, 77l and 77o.

167. Any person who did not acquire their Chembio shares directly in or traceable to the May Offering and pursuant to the Registration Statement is not included in the Class. Also excluded from the Class are Defendants, the officers and directors of the Company, members of their immediate families and their legal representatives, heirs, successors or assigns, and any entity in which Defendants have or had a controlling interest.

168. The members of the Class are so numerous that joinder is impracticable. The May Offering involved the issuance and sale of at least 2.6 million shares of Chembio stock, which were publicly traded on the NASDAQ following the May Offering.

169. While the exact number of Class members is unknown to Lead Plaintiffs at this time, Lead Plaintiffs believe that there are at least thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Chembio or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

170. Lead Plaintiffs' claims are typical of the claims of the Class, as all Class members were and are similarly affected by Defendants' conduct.

171. Lead Plaintiffs will fairly and adequately protect the interests of Class members and have retained counsel competent and experienced in securities class action litigation.

172. Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members. Among the common questions of law and fact are:

(a) whether Defendants violated the Securities Act;

(b) whether the Registration Statement misrepresented and/or omitted material facts in violation of the Securities Act; and

(c) whether and to what extent Class members have sustained damages and the proper measure of damages.

173. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy. Because the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it exceedingly difficult, if

not impossible and impracticable, for Class members to individually redress the alleged wrongs done to them. There will be no difficulty in managing this action as a class action.

COUNT I

For Violations of §11 of the Securities Act Against All Defendants

174. Lead Plaintiffs repeat and reallege the above allegations in ¶¶1-173 as if fully set forth herein.

175. This Cause of Action is brought pursuant to Section 11 of the Securities Act, 15 U.S.C. §77k, on behalf of the Class. This Cause of Action does not allege, and does not intend to allege, fraud or fraudulent intent, which is not a required element of Section 11, and any implication of fraud or fraudulent intent is hereby expressly disclaimed.

176. Section 11 gives rise to liability to certain defendants enumerated therein if "any part of the registration statement, when such part became effective, contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading. . . ." 15 U.S.C. §77k(a).

177. Among others, Section 11 identifies the following categories of defendants as those who may be liable thereunder: (a) "every person who signed the registration statement"; (b) "every person who was a director of (or person performing similar functions) . . . the issuer at the time of the filing of the part of the registration statement with respect to which his liability is asserted"; (c) "every person who, with his consent, is named in the registration statement as being or about to become a director, person performing similar functions, or partner"; and (d) "every underwriter with respect to such security." 15 U.S.C. §77k(a)(1)-(3), (5).

178. The prospectus and prospectus supplement, which were incorporated in and formed part of the Registration Statement for the May Offering, contained inaccurate and misleading

statements of material fact, omitted facts necessary to render statements therein non-misleading, and omitted to state material facts required to be stated therein.

179. Chembio is the registrant for the May Offering. Defendants named herein were responsible for the contents and dissemination of the Registration Statement, and the Director Defendants and Officer Defendants each signed and/or authorized the signing of the Registration Statement or were designated therein as director-nominees. The Underwriter Defendants marketed and underwrote the May Offering and sold Chembio common stock to investors.

180. As the issuer of the shares, Chembio is strictly liable to Lead Plaintiffs and the Class for the Registration Statement's material misstatements and omissions. Signatories of the Registration Statement and the other Defendants named herein are also liable to Lead Plaintiffs and the Class, subject to affirmative defenses, for such material misstatements and omissions.

181. The Registration Statement contained untrue statements of material fact and failed to disclose material facts, as detailed above. Defendants owed Class members a duty to make a reasonable and diligent investigation of the statements contained in the Registration Statement to ensure they were true and accurate. Defendants, in the exercise of reasonable care, should have known of the misstatements and omissions contained in the Registration Statement as set forth above, but none of Defendants named herein made a reasonable investigation or possessed reasonable grounds to believe that the statements in the Registration Statement were complete, accurate, or non-misleading.

182. By reason of the conduct alleged herein, each defendant violated, and/or controlled a person who violated, Section 11 of the Securities Act.

183. The Funds purchased Chembio common stock directly in the May Offering, on the Offering date and at the Offering price, pursuant to the Registration Statement.

184. Lead Plaintiffs and the Class have sustained damages. The value of Chembio common stock has declined following the May Offering and due to Defendants' violations.

185. At the time of their purchases of Chembio common stock, Lead Plaintiffs and other members of the Class were without knowledge of the facts concerning the wrongful conduct alleged herein.

186. Less than one year elapsed from the time that the Funds discovered, or reasonably could have discovered, the facts upon which this complaint is based to the time that Lead Plaintiffs filed this action. Less than three years has elapsed between the time that the securities upon which this Cause of Action is brought were offered to the public and the time this action was filed.

COUNT II

For Violations of §12(a)(2) of the Securities Act Against Chembio, Page, and the Underwriter Defendants

187. Lead Plaintiffs repeat and reallege the above allegations in ¶¶1-186 as if fully set forth herein.

188. This Cause of Action is brought pursuant to Section 12(a)(2) of the Securities Act, 15 U.S.C. §771(a)(2), on behalf of the Class, against Chembio, Page, and the Underwriter Defendants. This Cause of Action does not allege, and does not intend to allege, fraud or fraudulent intent, which is not a required element of Section 12(a)(2), and any implication of fraud or fraudulent intent is hereby expressly disclaimed.

189. Section 12(a)(2) gives rise to liability as to "[a]ny person who . . . offers or sells a security . . . by means of a prospectus or oral communication, which includes an untrue statement of a material fact or omits to state a material fact necessary in order to make the statements, in the light of the circumstances under which they were made, not misleading. . . ." 15 U.S.C. §771(a)(2).

190. Liability for a violation of Section 12(a)(2) extends to those, at a minimum, who passed title to the security to the purchaser, as well as those who solicited the purchase.

191. By means of the defective Prospectus and Prospectus Supplement, which was incorporated in and formed part of the Registration Statement for the May Offering, these Defendants promoted and sold, for the benefit of themselves and their associates, Chembio common stock to members of the Class. In the absence of their efforts to publicize the May Offering and solicit Chembio common stock purchasers, the May Offering could not have occurred.

192. Additionally, Chembio qualifies as a statutory seller under SEC Rule 159A, 17 C.F.R. §230.159A(a)(1)- (4), which provides that an issuer is a statutory seller for the purpose of Section 12(a)(2) regardless of the form of underwriting. The Rule provides, in part, the following "[d]efinition of seller for purposes of section 12(a)(2) of the [1933] Act":

> For purposes of section 12(a)(2) of the Act only, in a primary offering of securities of the issuer, regardless of the underwriting method used to sell the issuer's securities, seller shall include the issuer of the securities sold to a person as part of the initial distribution of such securities, and the issuer shall be considered to offer or sell the securities to such person, if the securities are offered or sold to such person by means of any [prospectus] . . . [or] other communication that is an offer in the offering made by the issuer to such person.

193. Furthermore, for the purpose of SEC Rule 159A(a), "information is provided or a communication is made by or on behalf of an issuer if an issuer or an agent or representative of the issuer authorizes or approves the information or communication before its provision or use." Note 1, 17 C.F.R. §230.159A(a); *see also* 70 Fed. Reg. 44722 at 44769 (Aug. 3, 2005).

194. The Registration Statement contained untrue statements of material fact and failed to disclose material facts, as detailed above. Defendants owed Class members a duty to make a reasonable and diligent investigation of the statements contained in the Registration Statement to ensure they were true and accurate. Defendants, in the exercise of reasonable care, should have known of the misstatements and omissions contained in the Registration Statement as set forth

above, but none of Defendants named herein made a reasonable investigation or possessed reasonable grounds to believe that the statements in the Registration Statement were complete, accurate, or non-misleading.

195. The Funds purchased Chembio common stock directly in the May Offering and pursuant to the Registration Statement.

196. The Funds did not know, nor in the exercise of reasonable diligence could have known, of the untruths and omissions contained in the Registration Statement when they purchased Chembio common stock.

197. By reason of the conduct alleged herein, these Defendants violated Section 12(a)(2) of the Securities Act. As a direct and proximate result of such violations, the Funds and other members of the Class who purchased Chembio common stock pursuant to the Registration Statement sustained substantial damages in connection with their purchases.

198. Accordingly, members of the Class who hold Chembio common stock issued pursuant to the Registration Statement have the right to rescind and recover the consideration paid for their shares, and hereby tender their Chembio common stock to the defendants sued herein. Class members who have sold their Chembio common stock seek damages to the extent permitted by law.

COUNT III

For Violations of §15 of the Securities Act Against the Officer Defendants and the Director Defendants

199. Lead Plaintiffs repeat and reallege the above allegations in ¶¶1-198 as if fully set forth herein.

200. This Cause of Action is brought pursuant to Section 15 of the Securities Act against the Officer Defendants and the Director Defendants. This Cause of Action does not allege, and does

not intend to allege, fraud or fraudulent intent, which is not a required element of Section 15, and any implication of fraud or fraudulent intent is hereby expressly disclaimed.

201. Where a violation of Section 11 or Section 12(a)(2) occurs, Section 15 gives rise to liability as to "[e]very person who, by or through stock ownership, agency, or otherwise, or who, pursuant to or in connection with an agreement or understanding with one or more other persons by or through stock ownership, agency, or otherwise, controls any person liable under sections 77k or 77l [§11 or §12(a)(2)]. . . ." 15 U.S.C. §77o(a). Control persons under Section 15 are "liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable. . . ." *Id*.

202. As detailed herein, each of the Director Defendants and Officer Defendants committed primary violations of the Securities Act, or are directly responsible and primarily liable for any such violations, through conduct that violates Sections 11 and 12(a)(2).

203. The Company controlled the Director Defendants and the Officer Defendants, each of whom signed the Registration Statement.

204. The Director Defendants and Officer Defendants each were control persons of Chembio by virtue of their positions as directors and/or senior officers of the Company. They each had direct and/or indirect business and/or personal relationships with other directors, officers and/or major shareholders of Chembio. Alternatively, the Company controlled the Director Defendants and the Officer Defendants, given the influence and control the Company possessed and exerted over them.

205. By reason of the conduct alleged herein, these Defendants violated Section 15 of the Securities Act, and members of the Class have suffered harm as a result.

PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiffs, on behalf of themselves and the other members of the Class, pray for relief and judgment as follows:

A. Determining that this action is a proper class action, certifying Lead Plaintiffs as Class Representatives under Rule 23 of the Federal Rules of Civil Procedure, and appointing Co-Lead Counsel as Class counsel;

B. Awarding compensatory damages in favor of Lead Plaintiffs and the other members of the Classes against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Lead Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees;

D. Awarding rescission or a rescissory measure of damages as to Count II; and

E. Awarding Lead Plaintiffs and other members of the Class such other and further relief as the Court may deem just and proper.

JURY DEMAND

Lead Plaintiffs hereby demand a trial by jury.

DATED: July 26, 2022

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Co-Lead Counsel for Lead Plaintiffs and the Putative Class

CERTIFICATE OF SERVICE

I, David A. Rosenfeld, hereby certify that on July 26, 2022, I authorized a true and correct copy of the foregoing document to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such public filing to all counsel registered to receive such notice.

/s/ David A. Rosenfeld
DAVID A. ROSENFELD